

**REMARKS**

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-23 are pending in this application.

**Rejections under 35 U.S.C. § 112**

Claims 1-6, 11-14 and 17-23 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Although Applicants do not necessarily agree with the Examiner's rejection, Although Applicants do not necessarily agree with the Examiners' rejection, Applicants have amended the claims taking into consideration the Examiners Comments.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 17-20 under 35 U.S.C. § 112, first paragraph.

Claims 1-6, 11-14 and 17-23 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although Applicants do not necessarily agree with the Examiners' rejection, Applicants have amended the claims taking into consideration the Examiners Comments.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-6, 11-14 and 17-23 under 35 U.S.C. § 112, second paragraph.

Claims 17-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserts claims 17-20 recite means (or step) plus function limitations and that the written description fails to disclose the corresponding structure. Applicants respectfully disagree.

Example embodiments are discussed throughout the subject specification and provide support for the “means for” limitations recited in claim 17. For example, the “memory means” reads on, at least, memory 12 as shown in FIG. 1 and paragraph [0043] of the subject specification. For example, the “input means” reads on, at least, computing device 25 as shown in FIG. 1 and paragraph [0054] of the subject specification. For example, the “reading means” reads on, at least, computing device 25 as shown in FIG. 1 and paragraph [0054] of the subject specification.

#### **Example Embodiments of the Present Application**

Independent claim 1 recites a method for carrying out a clinical study involving a patient comprising “reading by a computer associated with a non-study doctor assigned to the patient at least one of the study-related data and the patient-related data.” Example non-limiting embodiments of this feature

are discussed, for example, in paragraphs [0004]-[0010] and FIG. 1 of the subject specification.

A special study doctor is assigned to a patient who is extremely well informed about very strict and narrow marginal conditions with respect to the study. For example, the patient cannot be given certain medications if he/she continues to participate in the study.

A doctor who is not familiar with the study, for example the claimed non-study doctor assigned to the patient, does not know these restrictions and particular features of the clinical study relating to the patient. The example embodiments, however, deals precisely with this problem and solves this problem.

These problems do not occur with “normal medical actions” – e.g. as described in Brimm under “normal actions” in a hospital information system.

Example embodiments provide the particular study-related data, which clearly differ from normal patient data, in a suitable manner to a doctor who is not familiar with the study. The problem is solved according to example embodiments by providing a memory and/or an access authorization to the storage network which can be carried along by the patient.

As is illustrated in paragraphs [0052]-[0056] of the present application, serious health complications due to giving the patient 4 a drug are prevented by granting a non-study doctor access to memory 12. The non-study doctor 22 connects the memory 12 to their laptop 25. As indicated by arrows 27, the family doctor 22 reads the study data 14 and patient data 16 out from the memory 12 in an information step 26 and is thereby informed of the clinical

study 2 being carried out on the patient 4. From the study information 14, however, the non-study doctor determines that a drug is not compatible with the active agent of the clinical study. Therefore, the non-study doctor chooses a different drug that is compatible.

**Rejections under 35 U.S.C. § 103**

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,072,383 to Brimm et al. ("Brimm") in view of US Patent No. 5,417,222 to Dempsey ("Dempsey"). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner admits that Brimm does not disclose "the memory is one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the access being authorized by the patient," as recited by claim 1. The Examiner instead relies on Dempsey to disclose this limitation. Applicants respectfully disagree.

Dempsey discloses a portable telemetry unit including a monitor, a processor an I/O port and a transmitter/receiver. The telemetry unit does not include a memory. Inputs from a user may be passed through the I/O ports and the transmitter of the telemetry unit to a central station. A back channel may optionally be provided to permit information from the central station to be applied either to control the telemetry monitor or to be passed through the interface ports to the portable processor to provide information to a user. See Dempsey Abstract.

Further, even assuming *arguendo* that Dempsey discloses a memory, which Applicants do not admit, the memory does not store “study-related data associated with a protocol of the clinical study,” as required by claim 1. At most, Dempsey would store data as processed by the processor which would be related to data monitored by the physiological monitor. Although the Examiner relies on Brimm to disclose “study-related data associated with a protocol of the clinical study.” The Examiner is reminded of the requirements to consider the claim as a whole.

The Examiner is reminded that 35 U.S.C § 103(a) states “A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter **as a whole would have been obvious at the time the invention was made** to a person having ordinary skill in the art to which said subject matter pertains.”

Further, the Examiner is reminded that MPEP § 2106 instructs the Examiner as to how to determine the scope of a claim as “when evaluating the scope of a claim, every limitation in the claim must be considered. USPTO personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, **the claim as a whole must be considered**. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 188-89, 209 USPQ 1, 9 (1981)”

In addition, MPEP § 2141.02 requires that “ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and **considering both the invention and the prior art references**

**as a whole.** See MPEP § 2111 - § 2116.01 for case law pertaining to claim interpretation.” MPEP § 2141.02 further requires that “in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether **the claimed invention as a whole would have been obvious.** *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983).”

The Examiner is also directed to MPEP § 2143.01 which states “Obviousness can be established by combining or modifying the teachings of **the prior art** to produce the claimed invention where there **is some teaching, suggestion, or motivation to do so.** In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)”

Still further, MPEP § 2143.01 states:

A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). \*\*\*\*\*>[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. 398, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Emphasis original.

In rejecting claim 1, the Examiner has, at most, considered each element of the claim and recited art against each element. The Examiner has not

considered the claim as a whole. The Examiner has not considered the claims as a whole, at least, because the Examiner has provided no art disclosing a portable memory device to store clinical study data. Therefore, the Examiner has not recited art that teaches or fairly suggests “storing on a memory, study-related data associated with a protocol of the clinical study ... the memory is one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the access being authorized by the patient,” as required by claim 1.

For at least the reasons detailed above, Dempsey does not teach or fairly suggest “the memory is one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the access being authorized by the patient,” as required by claim 1.

For at least the reasons discussed above, Dempsey does not teach or fairly suggest “a memory to store at least one of study-related and patient-related data, the memory being a computer-readable medium assigned to the patient, the memory being one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the access being authorized by the patient,” as required by claim 7.

For at least the reasons discussed above, Dempsey does not teach or fairly suggest “the memory being a computer-readable medium assigned to the patient, the memory being one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the access being authorized by the patient,” as required by claim 17.

For at least the reasons described above, Brimm and Dempsey, alone and in combination (assuming *arguendo* that Dempsey could be combined with Brimm, which the Applicants do not admit) do not teach each and every limitation of claims 1, 7 and 17. Because Brimm and Dempsey do not teach or fairly suggest each and every limitation of independent claims 1, 7 and 17, Brimm in view of Dempsey does not render claims 1, 7 or 17 obvious. Claims 2-6, 8-16 and 18-23 are patentable at least by virtue of their dependency from an independent base claim.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-23 under 35 U.S.C. § 103(a).



**CONCLUSION**

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

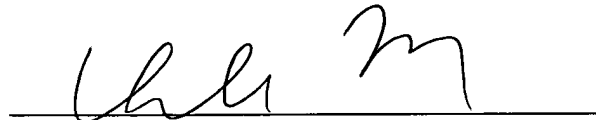
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By



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